

CAPIZONNE HAND SANITIZER- alcohol gel
Food Insixsigma, S.A. de C.V.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Capizonne Hand Sanitizer

DRUG FACTS

Active ingredient

Ethyl alcohol 70% v/v

Purpose

Antimicrobial

Use:

Hand sanitizer to help reduce bacteria on the skin.

Warnings

Flammable. Keep away from fire or flame. For external use only. Do not ingest, if swallowed seek medical help. Avoid contact with eyes.

Keep out of reach of children.

Children under 6yrs old to use under adult supervision. In case of irritation, discontinue use and consult your doctor.

Directions:

Apply the Gel on the hands and rub gently for 20 seconds until the product evaporates.

Other information:

Store below 106°F(41°C) May discolor certain fabrics or surfaces.

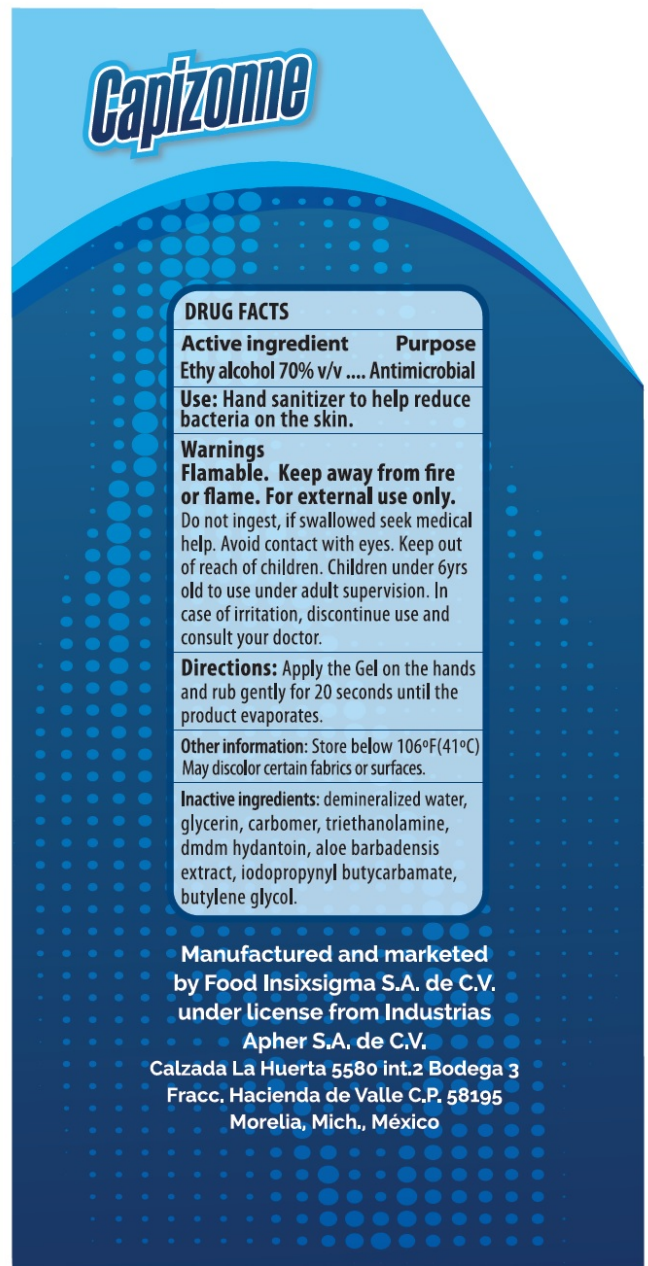
Inactive ingredients:

demineralized water, glycerin, carbomer, triethanolamine, dmdm hydantoin, aloe barbadensis extract, iodopropynyl butylcarbamate, butylene glycol.

Package Labeling:



FRENTE



REVERSO

CAPIZONNE HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80023-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80023-000-01	250 mL in 1 POUCH; Type 0: Not a Combination Product	07/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/13/2020	

Labeler - Food Insixsigma, S.A. de C.V. (812834608)

Establishment

Name	Address	ID/FEI	Business Operations
Food Insixsigma, S.A. de C.V.		812834608	manufacture(80023-000) , label(80023-000) , pack(80023-000)

Revised: 8/2020

Food Insixsigma, S.A. de C.V.